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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,857	08/14/2003	Scott Koenig	13783-105022	1191

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EXAMINER	
CROWDER, CHUN	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,857	KOENIG ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *108-130* is/are pending in the application.

4a) Of the above claim(s) *112-115, 119-122 and 125-130* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *108-111,116-118,123 and 124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I drawn to an antibody and species of clone 1F2 that is not conjugated, does not comprise a modification in the Fc region and antagonizes at least one activity of the FcγRIIB, filed 01/29/2007, is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, mailed 08/28/2006, the election has been treated as an election without traverse. See MPEP 818.03(a).

Claims 1-107 have been canceled.

Claims 108-130 have been added and are pending.

Claims 112-115, 119-122 and 125-130 have been withdrawn from further consideration by the Examiner under 37 C.F.R. 1.142(b) as being drawn to nonelected invention.

Claims 108-111, 116-118, 123, and 124 are currently under consideration as they read on the elected invention of an antibody and species of clone 1F2 that is not conjugated, does not comprise a modification in the Fc region and antagonizes at least one activity of the FcγRIIB.

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. Applicant's claim for domestic priority under 35 U.S.C. 119 (e) is acknowledged. However, the provisional application 60/403,266 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the claims of this application. Specifically, insufficient support was identified for the limitation of "clone 1F2". Consequently, the claims have been accorded the priority of the filing date of the instant application, i.e. 08/14/2003.

Should applicant disagree with the Examiner's factual determination above, it is incumbent upon applicant to provide a showing that specifically supports the instant claimed limitations.

4. Applicant's IDSs, filed 11/16/2004, 07/15/2005, and 09/01/2005 are acknowledged and have been considered except for reference C06 which has not been considered and has been crossed out because the date of the reference has not been provided.

5. Applicant's amendments to the specification, filed 01/29/2007, is acknowledged and have been entered.

6. The disclosure is objected to because of the use of trademarks (e.g. Herceptin on pages 116-119). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

In addition, Applicant is requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See MPEP § 608.01 and 608.01(p).

Further, the application is required to be reviewed and all spelling, TRADEMARK, and like errors corrected.

Appropriate correction is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 108-111, 116-118, 123, and 124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridoma clone 1F2 that produces the mouse monoclonal antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma 1F2, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

Applicant discloses on paragraph [00125] of the instant specification (see amendment to the specification filed 01/29/2007) that hybridoma 1F2 producing the claimed antibody has been deposited with ATCC under Budapest Treaty on 05/07/2004 (which is after the instant filing date 08/14/2003) with ATCC Accession number PTA-5959. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in US patent applications.

An affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma has been deposited under the Budapest Treaty and that the hybridoma *will be irrevocably and without restriction or condition released to the public upon the issuance of a patent* would satisfy the deposit requirement made herein. See 37 CFR 1.808.

Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806.

Given the deposit of hybridoma 1F2 was made on 05/07/2004 that is after the effective filing date of the application (08/14/2003), a verified statement is required from a person in a position to corroborate that the hybridoma 1F2 described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 116 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinrich et al. (Hybridoma. 1996, 15;2:109-116. Reference C67 in IDS) (See entire document).

Weinrich et al. teach that a monoclonal antibody II8D2, made from mice immunized with recombinant FcγRIIB, is specific for FcγRIIB without cross-reactivity with FcγRIIA in a well-known pharmaceutically acceptable carrier PBS based ELISA (see entire document, particularly Material and Method on pages 110-111 and Results on pages 111-114).

Given the prior art monoclonal antibody have the same antigen specificity as the claimed antibody produced from clone 1F2, the prior art antibody would compete for binding to FcγRIIB with the claimed mouse monoclonal antibody produced by clone 1F2.

Therefore, the reference teachings anticipate the claimed invention.

11. Claims 108-111, 116-118, 123 and 124 are rejected under 35 U.S.C. 102(e) as being anticipated by Stavenhagen et al. (US Patent Application 2005/0064514).

Stavenhagen et al. teach mouse monoclonal antibody, produced by hybridoma clone 1F2 having ATCC Accession number PTA-5959 (see entire document, particularly left column on page 42). Stavenhagen et al. further teach that the antibody can be chimeric, humanized and antibody fragments including $F(ab')_2$ and F(ab') (see page 11 in particular); the antibody can be formulated into a pharmaceutical composition comprising a therapeutically effective amount of the antibody and a pharmaceutically acceptable carrier (e.g. see pages 77-78).

Therefore, the reference teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinrich et al. (Hybridoma. 1996, 15;2:109-116. Reference C67 in IDS) in view of Pluckthun et al. (Immunotechnology 1997, 3:83-105).

The teachings of Weinrich et al. have been discussed, supra.

The reference teachings differ from the claimed invention by not describing antibody fragments $F(ab')_2$ and F(ab).

However, the methods of making antibody fragments and their advantages were well known in the art at the time the invention was made. For example, Pluckthun et al. teach that recombinant antibody fragments such as Fab, $F(ab')_2$, and Fv provide improved performance in vivo and in a variety of in vitro assays (see entire document, particularly pages 93-95 and Figure 6 on page 92).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to make antibody fragments including Fab, $F(ab')_2$, taught by Pluckthun et al. specific for FcγRIIB that can be used in immunoassys such as ELISA taught by Weinrich et al.; The ordinary artisan would have been motivated to do so because it is well know in the art at the time the invention was made to make antibody fragments for improved performance in vivo and in a variety of in vitro assays.

Given the teachings of Weinrich et al., providing method making and using antibody specific for the FcγRIIB, and the teachings of Pluckthun et al. regarding the antibody fragments, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success producing antibody fragments such as Fab, $F(ab')_2$, that binds specifically to the FcγRIIB.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 108-111, 116-118, 123, and 124 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-21, 23, 30-32, 38, 41-43, 81-90, and 104-109 of copending USSN. 11/305,787.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending applications claims are drawn to same or nearly the same anti-FcγRIIB antibody that specifically binds the extracellular domain of human FcγRIIB and/or anti-FcγRIIB antibody with Fc modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
March 14, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
3/14/07